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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,190	04/10/2001	Katsuya Matsuda	MATSUDA 13	4190

1444 7590 02/27/2004

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,190

Applicant(s)

MATSUDA ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Amendments filed and Rule 132 Declaration received on November 20, 2003 is acknowledged. Claims 29-52 are pending in this application. Claims 1-28 stand cancelled.

Response to Amendment

The Declaration under 37 CFR 1.132 filed November 20, 2003 is sufficient to overcome the rejection of claims 29-52 based upon Holmes-Farley et al (US patent 6,083,495).

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-30 and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Holmes-Farley et al (6,423,754).

Holmes-Farley et al disclose the method of preparing crosslinked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, and epichlorohydrin, yielding particles in a

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solution. The solid particles are then dried in a vacuum oven and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45.

*Although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant clearly states on page 10 of Applicant's Remarks that the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-32, 36, 41-43, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754).

Holmes-Farley et al disclose the method of preparing crosslinked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and column 3, lines 35-50. Suitable forms for administration are tablets, capsules, or powders. Further, the polymer may be administered alone or in combination with a carrier. See column 3, lines 35-60. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45.

Holmes-Farley et al does not exemplify the tablet formulation.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Holmes-Farley et al and utilize a tablet formulation containing the phosphate-binding polymer. One would be motivated to do so with the expectation of similar results since the prior art clearly teaches that the tablets are suitable form for administering the instant polymers. Therefore, one would be motivated to utilize the dosage form of choice depending on the desired type of administration.

Claims 33-40 and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Sato et al (5,202,335).

Holmes-Farley et al disclose the method of preparing crosslinked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See

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abstract and column 3, lines 35-50. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45.

Holmes-Farley does not specify the instant excipients: crystalline cellulose or HPC.

Sato et al teach succinic compounds for oral administration. Sato teaches that in molding pharmaceutical compositions into tablet formulations, many conventional carriers known in the art may be used. These carriers include lactose, sucrose, microcrystalline cellulose, etc. Sato also teaches the use of conventional disintegrators such as low-substituted HPC. The tablets may be coated with a sugar coating, gelatin coating, enteric coating, and film coating, depending on the desired effect. See column 8, lines 54-68. Sato teaches various suitable excipients for the composition that are known in the art. See column 9, lines 1-16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley et al and Sato et al. One would be motivated to do so since Sato teaches that instant tablet coat and instantly claimed excipients are conventional in the tableting art. Further, Sato teaches the functional equivalency of Holmes-Farley's suggested lactose carrier and instant

microcrystalline cellulose. Therefore, one would be motivated to substitute one carrier with another with a reasonable expectation of similar result. Additionally, skilled artisan would be motivated to coat the tablet depending on the desired effect of the composition, i.e. a sugar coat for a palatable tablet or a film coat for a smooth, glossy appearance.

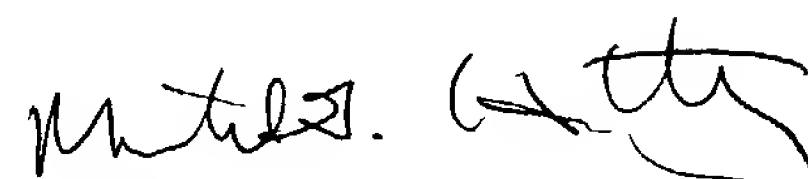
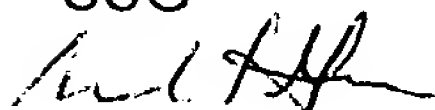
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG



MICHAEL G. HARTLEY
PRIMARY EXAMINER

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